UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GREGORY ATKINS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	**No. 3:16-cv-01954**
v.	)	**CHIEF JUDGE CRENSHAW**
	)	
TONY C. PARKER, *et al.*,	)	
	)	
Defendants.	)	

DEFENDANTS' PRETRIAL BRIEF

Pursuant to the Order of this Court (Doc. No. 219), Defendants Tony C. Parker, Commissioner of the Tennessee Department of Corrections ("TDOC"), and Kenneth L. Williams, M.D., Ph.D., TDOC Chief Medical Officer, by and through the Office of the Tennessee Attorney General, submit their pretrial brief.

EVIDENCE

The parties have stipulated that certain facts are uncontested and should be made a part of the evidentiary record at trial. (Doc. No. 198.) Those stipulated facts are incorporated herein by reference. Defendants' anticipated evidence at trial is further summarized as follows:

I. RONALD L. KORETZ, M.D.

Defendants will present the expert testimony of Ronald L. Koretz, M.D. (*See* Doc. No. 199-2, PageID 2541 [hereinafter "Koretz Report"].) Dr. Koretz is an Emeritus Professor of Clinical Medicine at the UCLA School of Medicine. Prior to 2006, Dr. Koretz was Chief of Gastroenterology at the Olive View–UCLA Medical Center. During his Gastroenterology Fellowship at UCLA in the 1970s, Dr. Koretz was part of a research team that was one of the first

to identify non-A, non-B Hepatitis, later identified as Hepatitis C. Dr. Koretz will present expert testimony related to the natural pathology of the Hepatitis C virus ("HCV")[1] and the necessity of using direct-acting antiviral drugs ("DAAs") to treat HCV as summarized below.

HCV is a viral infection that can cause inflammation of the liver. Over time, some patients develop scarring of the liver (fibrosis). Disease progression is commonly identified by reference to a patient's fibrosis score, which classifies the severity of fibrosis on a five-point scale ranging from F0 (no fibrosis) to F4 (cirrhosis). While the rate of disease progression is not the same in all patients with HCV, patients who develop cirrhosis generally do so over the course of decades. Many patients retain normal liver function even after developing cirrhosis (compensated cirrhosis); in other cirrhotic patients, liver function is compromised (decompensated cirrhosis). At that stage, patients are at risk of developing primary liver cancer, or hepatocellular carcinoma ("HCC"), and painful and life-threatening complications associated with end stage liver disease ("ESLD").

In discussing HCV management, it is important to distinguish between clinical tests that evaluate disease processes and those that evaluate actual liver function regardless of the underlying cause. The presence of HCV-RNA in a patient's blood serum is indicative of an active HCV infection. When a blood test 12 or 24 weeks after DAA treatment shows no detectable HCV-RNA in the serum, a patient is said to have achieved a sustained virologic response ("SVR"). Some medical providers state that the objective of HCV treatment is to remove HCV-RNA from the serum (to achieve SVR). But the primary goal of HCV treatment should be the prevention of ESLD. If DAA treatment truly prevents further progression of the disease, it should not matter when that treatment is provided as long as it is provided before any manifestation of ESLD.

[1] Unless otherwise indicated, Defendants' use of the acronym "HCV" in this brief refers to chronic HCV infection, as opposed to acute HCV infection.

Clinical guidelines published by the American Association for the Study of Liver Diseases and Infectious Diseases Society of America ("AASLD Guidance" or "AASLD Guidelines) recommend that all HCV-infected individuals should receive DAA treatment. While Plaintiffs' expert contends that this recommendation establishes the applicable standard of care, the AASLD Guidelines do not adhere to the principles of evidence-based medicine. Their treatment recommendations are not properly supported and do not establish the applicable standard of care. The AASLD Guidelines support their recommendations by citation to studies showing high rates of post-treatment SVR, which the AASLD Guidelines characterize as the marker for a cure.

SVR is not the equivalent of a cure. SVR has never been validated in a randomized controlled study showing that both the surrogate outcome (SVR) and the clinical outcome (long-term liver function) are similarly changed by the intervention of DAAs. (*See* **Def. Ex. 60,**[2] "Levels of Evidence Pyramid.") Some patients who achieve SVR still harbor HCV-RNA in other cells. In those patients, a genetically identical virus may reappear months or years after treatment and progress to ESLD. In fact, patients with fibrosis scores of F3 and F4 when SVR occurs subsequently develop ESLD at a rate of 2% per year. (*See* **Def. Ex. 61**, Figure – "How often does hepatic decompensation or HCC occur after SVR?") Studies associating SVR with better liver-related outcomes are subject confounding bias. SVR does not occur at random. The characteristics associated with a likelihood of achieving SVR are also characteristics associated with better health in general (such as younger age, normal weight, and absence of coinfections or substance abuse). In the absence of a randomized controlled study of the long-term effects of DAA treatment, it is impossible to say whether DAAs create better clinical outcomes or simply identify the subgroup

[2] Defendants were not able to identify exhibits by their corresponding exhibit numbers in the joint consolidated exhibit binder prior to the deadline for pretrial briefs. Defendants will submit a revised pretrial brief identifying each joint exhibit number as soon as possible.

that would have had better outcomes without treatment. To date, there has not been a randomized controlled study of the long-term effects of DAA treatment.

There is no convincing scientific evidence that treating patients with lower stages of fibrosis (F0 to F2) will result in any clinical benefit. Many patients with lower stages of fibrosis (F0 to F2) never progress to ESLD and would never need treatment. Periodic assessment of those patients is appropriate. Because it takes years or decades for fibrosis to progress, and because most patients with lower stages will never develop ESLD, it is a more rational policy to provide DAA treatment only to those who are at a high risk of developing ESLD, namely those with fibrosis scores of F3 and F4.

II. MARTHA S. GERRITY, M.D., M.P.H., PH.D.

Defendants will present the expert testimony of Martha S. Gerrity, M.D., M.P.H., Ph.D. (*See* Doc. No. 199-1, PageID 2309 [hereinafter "Gerrity Report"].) Dr. Gerrity is a Clinical Epidemiologist at the Center for Evidence-Based Policy at Oregon Health & Science University ("OHSU"). Dr. Gerrity is also a Professor of Medicine at OHSU and a staff physician at the VA Portland Health Care System. Her work is focused on improving patient care by translating and teaching basic principles of clinical research design and epidemiology for clinicians, patients, and policymakers, so they can better understand the strength and quality of research evidence and its role in their decision-making. Dr. Gerrity will present expert testimony related to the trustworthiness of the AASLD Guidance and its recommendations.

While frequently cited as setting forth the "standard of care" the AASLD Guidance does not meet the criteria for trustworthy guidelines promulgated by the Institute of Medicine. In 2016, the Center of Evidence-Based Policy at OHSU published a detailed assessment of the AASLD Guidance based on three widely accepted standards for trustworthy guidelines. (*See* Gerrity Report

at 152, PageID 2459.) Ten independent raters, with expertise in systematic review methods and/or research expertise in hepatology evaluated the AASLD Guidance and produced the following results: 7 of the 10 raters assessed the AASLD Guidance as having poor methodological quality; the evidence cited to support treatment recommendations did not follow rigorous systematic review methods; the AASLD Guidance did not adhere to standards for developing treatment recommendations, including those applicable to transparency in recommendation development, funding, and management of conflicts. Several raters expressly noted the lack of transparency with regard to managing conflicts of interest.

III. KENNETH L. WILLIAMS, M.D., PH.D.

Defendants will present the testimony of Kenneth L. Williams, M.D., Ph.D. Dr. Williams is the Chief Medical Officer and Director of Pharmacy for TDOC. He is responsible for ensuring that all the medical needs – not just those related to HCV – are met for each of TDOC's approximately 21,000 inmates. Dr. Williams is familiar with the challenges posed by HCV infection in prison populations and the available means of addressing the medical needs of HCV-infected inmates. Dr. Williams will testify regarding his development and implementation of systems that ensure the appropriate management of HCV in TDOC facilities. (*See generally* **Def. Ex. 1**, "Evaluation and Management of Chronic Hepatitis C (HCV) Infection, TDOC Clinical Guidance, May 2019," [hereinafter "HCV Guidance"]; **Def. Ex. 2**, "TDOC HCV Treatment Work Flow," [hereinafter, "HCV Workflow"].)

When the FDA first approved interferon-free DAAs for the treatment of HCV in 2013, some medical providers in TDOC facilities expressed reluctance to prescribe DAA treatment to HCV-infected inmates in their care. In response, Dr. Williams developed written guidance for the evaluation and management of HCV in TDOC facilities, dated January 2016, to provide

recommendations for testing, managing, and treating HCV in the inmate population. Dr. Williams also formed the TDOC Advisory Committee on HIV and Viral Hepatitis ("TACHH") to assist TDOC medical providers in recommending treatment for and to ensure consistent statewide treatment of HCV.

The TACHH meets at least once each month to review and consider the medical records of inmates referred to it by medical providers in TDOC facilities. As Chief Medical Officer of TDOC, Dr. Williams serves as chairman. The TACHH is further comprised of infectious disease specialists and other medical professionals. Upon referring an inmate for consideration by the TACHH, medical providers are directed to submit a packet containing the relevant medical records for that inmate to the TACHH Coordinator. (*See* **Def. Ex. 51**, "Medical Records Packet for Russell Davis for March 11, 2018 TACHH Meeting.") The TACHH provides centralized review of the medical records for each referred inmate to determine individual medical needs without reference to identifying information, disciplinary record, or basis for incarceration.

Since its inception, Dr. Williams has taken steps to expand the TACHH's capacity and to increase the number of inmates considered and recommended for DAA treatment. For example, in the past when the medical packet of a referred inmate did not contain all of the clinical information needed to make a specific treatment recommendation, the TACHH would identify what additional information was needed and make several alternative recommendations based on the possible results.[3] Dr. Williams determined, however, that medical providers in the TDOC facilities were hesitant to prescribe treatment in the absence of a specific recommendation from the TACHH. In response, Dr. Williams directed the TACHH Coordinator to ensure that the

[3] (*See, e.g.*, **Def. Ex. 24**, "TACHH Minutes dated November 27, 2017.") (Treatment recommendation for Craig Davis states "Refer to ID for Epclusa x 12 weeks plus or minus Ribavarin depending on [ultrasound].").

packets for each referred inmate contain all necessary clinical information needed for a specific treatment determination before the TACHH takes the inmate's case up for consideration.

Through these and other efforts aimed at increasing efficiency, the number of inmates considered and recommended for DAA treatment by the TACHH has consistently increased over time. In fiscal year 2017-2018, the TACHH recommended DAA treatment for 180 inmates. (*See* **Def. Ex. 47**, "Rule 1006 Chart Summarizing TACHH Meeting Minutes.") In the first 11 months of fiscal year 2018-2019 (through May 2019), the TACHH recommended DAA treatment for 242 inmates. (*See id.*)

Having sought and obtained significant additional funding from the General Assembly for the purchase of DAAs in April 2019, Dr. Williams has implemented additional systems to significantly increase the number of patients referred to and reviewed by the TACHH. (*See* **Def. Ex. 48**, "State of Tenn. Pub. Ch. 405;" **Def. Ex. 62**, "Recurring Budget Appropriation.") In December 2018, at the direction of Dr. Williams, TDOC implemented opt-out HCV testing of all inmates at intake. Dr. Williams also directed and guided TDOC's medical vendor, Centurion, in the development of an online registry to ensure that all pertinent information related to HCV testing and HCV-infected inmates is readily accessible to TDOC officials and medical providers throughout the State. The Hepatitis Online Registry ("HepCOR") launched in June 2019 and provides the TACHH with access to the clinical information it needs to make specific treatment recommendations for referred inmates. (*See* **Def. Ex. 3**, "HepCOR PowerPoint Slides.")

In May 2019, Dr. Williams issued an updated HCV Guidance for the evaluation and management of HCV in the TDOC population. (*See* **Def. Ex. 1**, HCV Guidance.) Shortly thereafter, Dr. Williams issued the HCV Workflow to provide additional direction for TDOC medical providers. (*See* **Def. Ex. 2**, HCV Workflow.) Together, the HCV Guidance and HCV

Workflow outline the current systems Dr. Williams has implemented to ensure proper management of HCV in the TDOC population.

All inmates are tested for HCV at intake unless they specifically decline testing or evidence of infection is already documented. (HCV Guidance § 1.1.) All previously untested inmates are offered HCV testing during periodic health appraisals and at the recommendation of clinicians secondary to appropriate signs and symptoms. (*Id.*) HCV testing is also made available upon inmate request. Inmates who refuse HCV testing are counseled about and offered HCV testing during periodic health visits. (*Id.* at § 1.3.) All relevant clinical information related to HCV testing and HCV-infected inmates is logged in HepCOR and is readily accessible online to TDOC medical providers throughout the State. (*Id.*) Known HCV-infected inmates are referred to the Project Echo education program coordinator to receive peer-to-peer education about the risks and prevention measures associated with communicable disease. (*See* **Def. Ex. 4**, "TDOC Policy No. 113.46 Inmate Peer Education Program.") All HCV-infected inmates receive a baseline evaluation – comprising of a targeted history and physical examination and lab tests – within two months of testing. (*Id.* at § 2.1.) All HCV-infected inmates also undergo an assessment of liver condition to determine the need for treatment and other interventions. (*Id.* at § 3.) Medical providers use preferred noninvasive methods of assessing fibrosis and cirrhosis, including FibroScan elastography, (*id.* at § 3.1.3), which Plaintiffs' expert characterizes as "the current gold standard for diagnosis." (Doc. No. 204-1 at 14, PageID 2734.) (*See* **Def. Ex. 5**, "FibroScan Operator Training Presentation;" **Def. Ex. 53**, "FibroScan Report of Tom Rollins.")

TDOC medical providers refer all HCV-infected inmates for consideration by the TACHH, which is comprised of infectious disease experts and other health care professionals who make specific treatment recommendations based on the medical needs of each referred inmate. (*Id.* at §

4.) The TACHH Coordinator reviews the medical packet of each referred inmate to ensure it is complete. (HCV Workflow at 3.) The TACHH Coordinator returns incomplete medical packets to the medical provider with instructions to supply the missing information within 10 days. (*Id.*) The TACHH Coordinator presents complete packets of all referred inmates to the TACHH for review and treatment recommendations. (*Id.*) Within seven days after each TACHH meeting, the TACHH Coordinator emails the meeting minutes and consult report to the medical providers. (*Id.*) Within three days after receiving the consult report, the medical provider must write orders to effectuate the TACHH recommendation. (*Id.*) Within five days after receiving the consult report, the infectious care nurse must follow up to ensure the order has been written and processed. Within ten days after the order is written, the nurse must verify medication has started or inform appropriate staff of a delay. (*Id.*)

All HCV-infected inmates, regardless of their DAA treatment status, are evaluated at least every six months to monitor disease progression. (HCV Guidance at § 6.) Inmates recommended for DAA treatment are also evaluated at regular intervals before and during DAA treatment to monitor adherence, possible adverse reactions. (HCV Guidance at §§ 5.1, 5.2.) Inmates are similarly evaluated after DAA treatment to assess for SVR. (*Id.* at 5.3.) Even when SVR is achieved after DAA treatment, inmates with F3 and F4 fibrosis are evaluated every six months to monitor for hepatocellular carcinoma. (HCV Workflow at 4.)

Dr. Williams has secured from the General Assembly a one-time allocation of $24,678,700 for the purchase of DAAs. (*See* **Def. Ex. 48**, "State of Tenn. Pub. Ch. 405.") Those funds are in addition to TDOC's recurring allocation of $4,600,000 for the purchase of DAAs. (*See* **Def. Ex. 62**, "Recurring Budget Appropriation.") They are also in addition to $2,000,000 in matching funds Centurion is contractually required to provide annually for the purchase of DAAs. (*See* **Def. Ex.**

63, "Contract Between TDOC and Centurion.") In addition, DAA prices have dropped significantly in recent years. (See **Def. Ex. 54**, "Clinical Solutions DAA Pricing Info;" **Def. Ex. 55**, "Hepatitis C Pharmacy Costs Sheet.") That fact, in conjunction with TDOC's increased funding for the purchase of DAAs and the extensive efforts of Dr. Williams to increase the efficiency and capacity of the TACHH, the number of HCV-infected inmates receiving DAA treatment is expected to increase significantly going forward.

In addition to the exhibits referenced above, Dr. Williams may testify regarding the monthly HCV-HIV Dashboard he uses to track patient care, (see **Def. Ex. 49**, "May 2019 HCV-HIV Dashboard"), as well as exhibits submitted as examples of inmate medical records and medication administration records. (See **Def. Ex. 50**, "Medical Records of Kevin Profitt;" **Def. Ex. 52**, "Medical Administration Record of Russell Davis.")

IV. TDOC COMMISSIONER TONY C. PARKER

Defendants may present the testimony of TDOC Commissioner Tony C. Parker. Commissioner Parker supervises administrative functions of the TDOC in conjunction with the Governor and General Assembly. Commissioner Parker also supervises Dr. Williams indirectly through the Assistant Commissioner of Rehabilitative Services. Commissioner Parker has no medical training and is not involved in the development of protocols for the provision of medical care in TDOC facilities.

V. TDOC CHIEF FINANCIAL OFFICER WES LANDERS

Defendants may present the testimony of TDOC Chief Financial Officer Wes Landers. Mr. Landers has knowledge of TDOC's financial and budgetary operations. Mr. Landers also has knowledge of the appropriation of funds from the General Assembly for the purchase DAAs. (*See* **Def. Ex. 48**, "State of Tenn. Pub. Ch. 405;" **Def. Ex. 62**, "Recurring Budget Appropriation.")

LAW

Plaintiffs seek declaratory and injunctive relief under 42 U.S.C. § 1983 for an alleged violation of their Eighth Amendment rights. (Doc. No. 1 at 1, PageID 1.) Section 1983 provides a federal cause of action against government officials who, acting under color of state law, have "deprived the claimant of rights, privileges or immunities secured by the Constitution or laws of the United States." *Bennett v. City of Eastpointe*, 410 F.3d 810, 817 (6th Cir. 2005). The parties stipulate that Defendants have acted under color of law at all times relevant to this case (Doc. No. 219 at 2, PageID 2903), but Defendants deny the allegations of a constitutional violation.

Plaintiffs are not entitled to a declaration concerning the adequacy of Defendants' past actions. *Green v. Mansour*, 474 U.S. 64, 68-69 (1985). Similarly, a court may not grant prospective injunctive relief in the absence of continuing violation of federal law. *Id.* The proper inquiry is therefore not whether Defendants acted unconstitutionally in the past, or even during the pendency of this litigation, but whether Defendants' actions are unconstitutional at the time that the Court acts. *Golden v. Zwickler*, 394 U.S. 103, 108 (1969); *Midwest Media Prop., L.L.C. v. Symmes Tp., Ohio*, 503 F.3d 456, 460 (6th Cir. 2007).

"Wide-ranging deference must ordinarily be accorded to the decisions of prison administrators." *Grubbs v. Bradley*, 821 F.Supp. 496, 502 (M.D. Tenn. 1993). "Absent a clear finding of constitutional violations, federal courts simply will not interfere with the state's administration of its prison system." *Id.* Even when a violation has occurred, relief a federal court may only grant prospective relief upon finding that such relief is "narrowly drawn, extends no further than necessary to correct the violation," and "is the least intrusive means necessary to correct the violation." 18 U.S.C. § 3626(a)(1). The court must also "give substantial weight to any adverse impact on . . . the operation of a criminal justice system caused by the relief." *Id.*

I. THE EIGHTH AMENDMENT

The Supreme Court has held that the Eighth Amendment's ban on cruel and unusual punishments establishes "the government's obligation to provide medical care for those whom it is punishing by incarceration." *Estelle v. Gamble*, 429 U.S. 97, 103 (1976). Because the Court has also held that "only the unnecessary *and wanton* infliction of pain implicates the Eighth Amendment," however, a constitutional violation does not arise when there is a mere failure to provide adequate medical care. *Wilson v. Seiter*, 501 U.S. 294, 296-97 (1991) (emphasis by the Court). Rather, a constitutional violation arises only *when* prison official exhibits "deliberate indifference to prisoner's serious illness or injury," *Estelle*, 429 U.S. at 105, that can be characterized as "obduracy and wantonness, not inadvertence or error in good faith." *Wilson*, 501 U.S. at 299 (citations omitted).

To establish an Eighth Amendment deliberate indifference claim, a plaintiff must satisfy two components: one objective, and the other subjective. *Farmer v. Brennan*, 511 U.S. 825, 834 (1994). The plaintiff must show both that the alleged deprivation was objectively harmful enough to establish a constitutional violation and that the prison official acted with a culpable state of mind rising above gross negligence. *Id.* at 834-35. Defendants address each component separately.

II. OBJECTIVE COMPONENT

At the outset, Defendants acknowledge that HCV is serious medical *condition*.[4] The existence of a serious medical condition alone, however, is not conclusive under the objective

[4] As explained herein, case law recognizes the distinction between a serious medical condition and a serious medical need. Defendants do not stipulate that members of the Plaintiff class have been deprived of a serious medical need sufficient to satisfy the objective component of their Eighth Amendment claim. Defendants' position on this issue has not changed throughout the litigation. (*See* Doc. No. 108 at 8, Page ID 1144.) To the extent that the Court's pretrial order indicates otherwise, it does not accurately represent Defendants' position as stated during the pretrial conference. (Doc. No. 219 at 2, PageID 2903.)

component. "The objective component requires a plaintiff to prove *that the alleged deprivation of medical care* was serious enough to violate the Eighth Amendment." *Rhinehart v. Scutt*, 894 F.3d 721, 737 (6th Cir. 2018) (emphasis added) (citing *Farmer*, 511 U.S. at 834). The analysis must focus on the challenged deprivation of treatment and the harm resulting from it, not the underlying medical condition alone.[5]

The Sixth Circuit distinguishes "between cases where the complaint alleges a complete denial of medical care and those cases where the claim is that a prisoner received inadequate medical treatment." *Alspaugh v. McConnell*, 643 F.3d 162, 169 (6th Cir. 2011). In the first instance, the inquiry may be a simple one. For example, when an inmate is diagnosed with a medical condition mandating treatment, the objective component may be satisfied by showing that prison officials failed to provide any treatment or provided treatment "so cursory as to amount to no treatment at all." *Rhinehart*, 894 F.3d at 737. In such cases, where the harm is "so obvious that even a layperson would easily recognize the necessity for a doctor's attention," the objective component may be satisfied without expert testimony showing how the alleged deprivation worsened or deteriorated the medical condition. *Blackmore v. Kalamazoo Cnty.*, 390 F.3d 890, 899-900 (6th Cir. 2004). "The Sixth Circuit has since made it clear," however, that cases in which deprivation of a serious medical need may be established without expert proof are an "exception to the general rule requiring medical proof to substantiate an Eighth Amendment medical indifference claim." *Shough v. Mgmt. & Training Corp.*, No. 3:16-cv-53, 2018 WL 295576, at *9 (N.D. Ohio Jan. 3, 2018).

[5] *See, e.g.*, *Smith v. Carpenter*, 316 F.3d 178, 186 (2nd Cir. 2003) ("[T]he District Court properly focused on the particular risks attributable to the missed HIV medication, rather than on Smith's HIV-positive status alone, in evaluating the jury's finding that Smith failed to demonstrate a serious medical need.").

When an inmate "has received some medical attention and the dispute is over the adequacy of the treatment," the objective component requires a substantial evidentiary showing. *See Darrah v. Krisher*, 865 F.3d 361, 372 (6th Cir. 2017) ("[F]ederal courts are generally reluctant to second guess medical judgments and to constitutionalize claims which sound in state tort law"). First, the inmate must show that the medical care provided was "so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness." *Rhinehart*, 894 F.3d at 737 (quoting *Miller v. Calhoun Cnty.*, 555 F.3d 803, 819 (6th Cir. 2005)). "This will often require 'expert medical testimony . . . showing the medical necessity for' the desired treatment and 'the inadequacy of the treatments' the inmate received." *Id.* at 737-38 (quoting *Anthony v. Swanson*, 701 F App'x 460, 464 (6th Cir. 2017)). Second, the inmate "must 'place verifying medical evidence in the record to establish the detrimental effect' of the inadequate treatment." *Id.* at 738 (quoting *Blackmore*, 390 F.3d at 898).

The Sixth Circuit's opinion in *Rhinehart v. Scutt*, 894 F.3d 721 (2018), illustrates these principles. In that case, a Michigan inmate diagnosed with ESLD filed suit alleging that prison doctors denied him necessary treatment in violation of the Eighth Amendment. *Id.* at 727. While the suit was pending in the district court, the inmate died due to his liver's failure to metabolize morphine prescribed for his pain, and his estate was substituted as the plaintiff. *Id.* at 734. The defendant doctors filed a motion for summary judgment on the plaintiff's deliberate indifference claims. *Id.* The district court ruled that, because the inmate received some treatment for his ESLD, his estate was required to present verifiable medical evidence showing the specific harm that resulted from the alleged inadequate treatment. *Id.* The district court determined that the plaintiff had not done so and granted the defendants motion for summary judgment. *Id.* On appeal, the plaintiff argued that treatment the inmate had received from the defendants was so cursory as to

amount to no treatment at all. *Id.* at 739. The Sixth Circuit appellate court disagreed, noting that the defendant doctors regularly examined the inmate, noted his liver disease, monitored his condition, evaluated and treated his symptoms, performed lab tests, MRIs, and CT scans, and prescribed beta blockers to reduce his blood pressure. *Id.* at 740. As a result, "[n]o reasonable jury could find that [the inmate's] ESLD treatment amounted to no treatment at all," and his estate was required to present medical evidence showing that his care was "so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness." *Id.* The court concluded that the plaintiff failed to do so and affirmed the district court's grant of summary judgment to the defendants. *Id.* at 745, 752-53.

Plaintiffs here, like the plaintiff in *Rhinehart*, clearly receive medical care for their condition. The HCV Guidance and HCV Workflow outline the systems Defendants have implemented to ensure proper screening, diagnosis, and management of HCV in the TDOC inmate population. Plaintiffs challenge the adequacy of that care provided for in those systems. (*See* Doc. No. 32 at 6, PageID 265 ("Plaintiffs contend that the central and common factual question at issue here is whether TDOC's treatment protocols and policies adequately screen for, diagnose and treat inmates with Hepatitis C.")). Plaintiffs' HCV-infected status alone is therefore insufficient to satisfy their burden under the objective component of an Eighth Amendment claim. Plaintiffs must show that the medical care provided is so grossly inadequate as to shock the conscience and must place verifying medical evidence in the record to establish the detrimental effect of that care. They can do neither.

A. Plaintiffs cannot show that the medical care they will receive is inadequate.

Plaintiffs contend that that Defendants' policies and practices related to HCV are inadequate because they do not provide universal DAA treatment for all HCV-infected inmates

regardless of fibrosis score. Plaintiffs' expert cites the AASLD Guidance and the studies cited therein as support for his assertion that universal DAA treatment is the current standard of care in the medical community. (Doc. No. 204-1 at 8-9, PageID 2728-29.) He asserts that these "new medications are enabling more patients to reach the virological cure (SVR)." (*Id.* at 8, PageID 2728.) The AASLD Guidance is aspirational and only sets forth recommendations for optimal care. Moreover, Drs. Koretz and Gerrity extensively outline flaws in both the AASLD Guidance and the scientific studies underlying its treatment recommendations. They explain that SVR is a surrogate outcome and does not constitute a "cure." Some patients who achieve SVR still harbor HCV-RNA in other cells. In those patients, a genetically identical virus may reappear months or years after treatment and progress to ESLD. Because preventing ESLD, not achieving SVR, should guide treatment decisions, individuals at greater risk for developing ESLD should be prioritized for DAA treatment.

Plaintiffs' expert states that there is no medical basis to support prioritizing individuals with more advanced fibrosis for DAA treatment. Plaintiffs' expert report states, "When DAAs were first approved, there was need to get immediate treatment to those in the early stages of liver disease." (Doc. No. 204-1 at 9, PageID 2729.) That statement is directly contradicted by the early version of the AASLD Guidance attached as an exhibit to his expert report, which states that where resources are limited, "prioritization of immediate treatment . . . is recommended [for] patients with progressive liver disease (Metavir stage F3 or F4)." (Id. at 62, PageID 2782.) That approach is consistent with the recommendations of Drs. Koretz and Gerrity and the policies and practices implemented by Dr. Williams.

Moreover, there are express related to the unknown long-term effects and effectiveness of DAA treatment. For example, as Dr. Koretz notes in his report, concerns about reactivation of

Hepatitis B in patients with coinfection resulted in the FDA requiring a black box warning be added to the drug labels of DAAs. Plaintiffs have presented to no evidence to counter those concerns. In Section 5 of his Supplemental Report, titled "Long-term benefit of HCV DAA treatment," Plaintiffs' expert quotes several sentences extolling the benefits of DAA treatment from the abstract summary of an article titled, "Reversion of disease manifestations after HCV eradication." (Doc. No. 204-2, PageID 2803.) The abstract summary is attached as an exhibit to his supplemental report and reveals that the very next sentence after that quoted passage states, "How these short-term results translate into a prolonged (long-term) survival has yet to be determined." (*Id.* at 12, PageID 2813.) Another abstract summary attached to the Supplemental Report notes that "data on-long term outcomes in HCV patients treated by DAAs are limited and complex," and "[w]ell designed studies with robust comparisons are needed to determine the effect of DAAs on the recurrence of HCC in the future." (*Id.* at 15, PageID 2816.) Other attached articles note that "impact of DAAs on hepatocellular carcinoma (HCC) development (de novo and recurrence) is still controversial," (*Id.* at 17, PageID 2818), and that "the benefits in terms of overall survival (OS) remains to be conclusively demonstrated." (*Id.* at 20, PageID 2821.) These statements provide direct support for the concerns regarding the uncertain long-term effects of DAA treatment.

Finally, Plaintiffs' expert states that universal DAA treatment is necessary for to achieve the public health goal of HCV elimination. (Doc. No. 204-1 at 12, PageID 2732.) As other federal courts have recognized, HCV elimination – while a "commendable and desirable" goal – "do[es] not provide a standard for evaluating deliberate indifference in the prison system." *Buffkin v. Hooks*, No. 1:18-cv-502, 2019 WL 1282785, at *7 (M.D. N.C. Mar. 20, 2019). The Eighth Amendment "does not guarantee that a prison inmate receive the optimum or best medical

treatment." *Bumpas v. Corr. Corp. of Am.*, No. 3:10-cv-1055, 2013 WL 830718, at *6 (M.D. Tenn. Feb. 1, 2013). Plaintiffs' evidence simply will not support a finding that, absent universal DAA treatment, the medical care they will receive under TDOC's current policies and practices related to HCV is so grossly inadequate as to shock the conscience.

B. Plaintiffs cannot show the detrimental effect of the alleged inadequate treatment.

Even if Plaintiffs could show that they receive grossly inadequate medical care, they must present verifying medical evidence to establish the detrimental effect of that care. Plaintiffs can present no such evidence. Plaintiffs' expert states that, without DAA treatment, HCV-infected individuals will continue to progress towards cirrhosis and will face an increasing risk of serious complications. (Doc. No. 204-1 at 9, PageID 2729.) While Drs. Koretz, Gerrity, and Williams all acknowledge that HCV may be associated with serious complications, they note that such conditions generally do not manifest until the individual develops ESLD. To state that untreated patients face an increased risk of developing serious complications, without reference to particular stages of disease progression, is insufficient to show the detrimental effect of limiting DAA treatment to individuals with advanced fibrosis or cirrhosis (F3 and F4). The primary goal of HCV treatment should be the prevention of ESLD; if DAA treatment prevents further progression of the disease, it should not matter when treatment is provided as long as patients receive it before developing ESLD. Because most individuals with HCV will never progress to ESLD, and those who do will generally do so over the course of decades, active surveillance of disease progression is sufficient for patients without advanced fibrosis (F0 to F2). That approach is consistent with the recommendations of Drs. Koretz and Gerrity and the care Plaintiffs' receive pursuant to the policies and practices implemented by Dr. Williams. Absent verifying medical evidence to

establish the detrimental effect of that care, Plaintiffs cannot show that they are deprived a serious medical need sufficient to satisfy the objective component of an Eighth Amendment claim.

III. SUBJECTIVE COMPONENT

Likewise, Plaintiffs cannot satisfy the subjective component of an Eighth Amendment claim. In addition to showing an objectively serious deprivation, a plaintiff must show that the defendants acted with a "sufficiently culpable state of mind." *Farmer*, 511 U.S. at 834. Errors in medical judgment or other negligent missteps will not support a deliberate indifference claim. *Estelle*, 429 U.S. at 107-08. Rather, the plaintiff must show that each defendant acted with mental state "equivalent to criminal recklessness." *Rhinehart*, 894 F.3d at 738 (quoting *Santiago*, 734 F.3d at 591). A prison official's "failure to alleviate a significant risk that he should have perceived but did not, while no cause for commendation, cannot under our cases be condemned as the infliction of punishment." *Farmer*, 511 U.S. at 838. The plaintiff must present evidence showing that the defendant "subjectively perceived facts from which to infer substantial risk to the prisoner, that he did in fact draw the inference, and that he then disregarded that risk" by failing to take reasonable steps to abate it. *Rhinehart*, 894 F.3d at 738 (quoting *Comstock v. McCrary*, 273 F.3d 693, 703 (6th Cir. 2001)).

In addition to showing that each defendant had subjective knowledge of the risk, the plaintiff also must show "that each defendant 'so recklessly ignored the risk that he was deliberately indifferent to it.'" *Id.* (quoting *Cairelli v. Vakilian*, 80 F. App'x 979, 983 (6th Cir. 2003)). "A doctor is not liable under the Eighth Amendment if he or she provides reasonable treatment, even if the outcome of the treatment is insufficient or even harmful." *Id.* (citing *Farmer*, 511 U.S. at 844). Because doctors are bound by the Hippocratic Oath, not applicable to other prison officials, the Court should defer to their medical judgment. *Id.* (citing *Richmond v. Huq*,

885 F.3d 928, 940 (6th Cir. 2018) ("[T]his Court is deferential to the judgments of medical professionals.")). While a doctor may not claim immunity by merely providing some treatment, "there is a high bar that a plaintiff must clear to prove an Eighth Amendment medical-needs claim: The doctor must have '*consciously* exposed the patient to an *excessive* risk of serious harm.'" *Id.* (emphasis by the court) (quoting *Richmond*, 885 F.3d at 840).

Disagreement among physicians as to the appropriate course of treatment is insufficient to establish deliberate indifference. *See Rhinehart*, 894 F.3d at 750-51; *see also Estelle*, 429 U.S. at 107 ("But the question whether . . . forms of treatment [are] indicated is a classic example of a matter for medical judgment."); *Rhinehart v. Scutt*, 509 F. App'x 510, 513 (6th Cir. 2013) ("Neither negligence alone, nor a disagreement over the wisdom or correctness of a medical judgment is sufficient for the purpose of a deliberate indifference claim.). Thus, "failure to follow an outside specialist's recommendation does not necessarily establish inadequate care." *Rhinehart*, 894 F.3d at 742.

The Fifth Circuit states that principle as follows: "There is no intentional or wanton deprivation of care if a genuine debate exists within the medical community about the necessity or efficacy of that care." *Gibson v. Collier*, 920 F.3d 212, 220 (5th Cir. 2019). Of course, a single dissenting expert does not automatically defeat medical consensus about whether particular treatment is necessary in the abstract. *Id.* But where there is "robust and substantial good fair disagreement dividing respected members of the expert medical community, there can be no claim under the Eighth Amendment." *Id.*

This subjective component of a deliberate indifference claim must be addressed individually for each defendant. *Rhinehart*, 894 F.3d at 738. Defendants therefore address the claims against Defendants Parker and Williams separately with the foregoing principles in mind.

A. Commissioner Parker

Plaintiffs cannot establish that Defendant Parker has the requisite subjective mental state to support a deliberate indifference claim. Commissioner Parker supervises administrative functions of the TDOC in conjunction with the Governor and General Assembly. He supervises Dr. Williams indirectly through the Assistant Commissioner of Rehabilitative Services. Commissioner Parker has no medical training and is not involved in the development of protocols for the provision of medical care in TDOC facilities. Commissioner Parker relies on the professional judgment of medical professionals employed by TDOC to make decisions concerning policies and practices for HCV management.

A supervisory official's failure to properly supervise, control, or train an individual is not actionable under Section 1983 unless the supervisor "either encouraged the specific incident of misconduct or in some other way directly participated in it." *Shehee v. Luttrell*, 199 F.3d 295, 300 (6th Cir. 1999). Moreover, non-medically trained prison officials do not act with deliberate indifference when they have "reasonably deferred to the medical professionals' opinions." *Olmstead v. Fentress Cnty.*, No. 2:16-cv-46, 2019 WL 1556657, at *8 (M.D. Tenn. April 10, 2019) (quoting *McGaw v. Sevier Cnty.*, 715 F. App'x 495, 497 (6th Cir. 2017)). As a supervisory prison official, Commissioner Parker is "entitled to rely on medical judgments made by medical professionals responsible for prisoner care." *Id.* Having done so, Plaintiffs cannot show that he has the subjective medical state required to support their Eighth Amendment claim against him.

B. Dr. Williams

As TDOC's Chief Medical Officer, Dr. Williams is responsible for ensuring that all the medical needs – not just those related to HCV – are met for each of TDOC's approximately 21,000 inmates. Dr. Williams developed and implemented systems design to ensure proper management

of HCV infection in the TDOC facilities as outlined in the HCV Guidance and HCV Workflow. Dr. Williams also secured more than $30 million in funding for the purchase of DAAs. Plaintiffs must show that, despite those efforts, Dr. Williams has demonstrated indifference to the medical needs of HCV-infected inmates with a culpable state of mind akin to criminal recklessness. They cannot make such a showing.

Dr. Williams has knowledge of the risks associated with HCV, but the evidence does not support a finding that he has disregarded those risks, much less that he has disregarded those risks with the subjective obduracy and wantonness required to show deliberate indifference. Dr. Williams has implemented opt-out HCV screening at intake, and HCV screening is available to all inmates upon request. Dr. Williams knows that acute HCV is cleared without intervention in approximately 15-25% of infected patients; in patients who do not clear the virus spontaneously, only 5-10% develop cirrhosis and those who do generally only do so over the course of 15 to 30 years, typically progressing from F2 to F3 over the course of 12 years. Dr. Williams knows that patients progress linearly and cannot bypass fibrosis stages; that is, a patient cannot progress from F0 to F4 without progressing through the other stages. Dr. Williams also knows that the long-term effects and effectiveness of DAA treatment are unknown. It is Dr. Williams's view that DAA treatment is not medically necessary in all patients in earlier stages of fibrosis (F0 to F2). Rather, active surveillance of disease progression constitutes adequate medical care.

As demonstrated by the differing opinions outlined in the previous section, there is robust and substantial good faith disagreement dividing respected members of the expert medical community regarding the necessity of providing DAA treatment to patients in earlier stages of fibrosis (F0 to F2). The materials attached to the supplemental expert report of Plaintiffs' expert demonstrate that is also substantial disagreement as to the long-term effects and potential long-

term harms of DAA treatment. To the extent that Dr. Williams has decided against prioritizing all HCV-infected inmates with fibrosis scores of F0 to F2 for DAA treatment, that decision is well-within the bounds of his discretionary judgment as a medical professional and cannot form the basis of a deliberate indifference claim.

Moreover, the naked assertion that Dr. Williams has considered cost and resource limitations in conjunction with decisions within his medical judgment does not suffice to state a claim for deliberate indifference. "[P]risoners do not have a constitutional right to limitless medical care, free of cost constraints under which law-abiding citizens receive treatment. *Hendricks v. Kasich*, 2:12-cv-729, 2014 WL 2006800, at *11 (S.D. Ohio May 16, 2014) (quoting *Winslow v. Prison Health Srvs.*, 406 F. App'x 671, 674 (3rd Cir. 2011)). "Resources are not infinite and reasonable allocation of those resources, taking into account cost, does not amount to deliberate indifference even if a prisoner does not receive the most costly treatments or his treatments of choice." *Id.* (quoting *Kietz v. Washington Cnty.*, No. 2:13-cv-507, 2014 WL 1316129, at *13 (W.D. Penn. Mar. 31, 2014)). To state an Eighth Amendment claim, a plaintiff must establish that a defendant performed a medical procedure for the purposes of cost savings with knowledge that the procedure was ineffective. *Casanova v. Mich. Dep't of Corr.*, No. 2:10-cv-13950, 2011 WL 4374457, at *3 (E.D. Mich. Sept. 20, 2011) (citing *Johnson v. Doughty*, 433 F.3d 1001, 1013 (7th Cir. 2006)). As explained above, Plaintiffs cannot make the required showing.

IV. RECENT DECISIONS OF OTHER COURTS

Defendants are aware that of class action litigation in which federal courts have found the departments of correction of our sister states were deliberately indifferent based on their failure to provide universal DAA treatment. Those cases are readily distinguishable from the case at bar,

however, because the records in each case were completely devoid of any evidence to show that universal DAA treatment is not medically necessary.[6]

Plaintiffs have submitted to the Court the decision in *Hoffer v. Inch*, No. 4:17-cv-214, 2019 WL 1747074 (N.D. Fla. Apr. 18, 2019), *appeal docketed*, No. 19-11921 (11th Cir. May 17, 2019). In that case, the district court entered a preliminary injunction requiring the Florida Department of Correction ("FDC") to its own policies related to HCV treatment then resolved on cross-motions for summary judgment. *Id.* at *1. The court found that FDC was deliberately indifferent to HCV-infected inmates and entered a broad permanent injunction requiring FDC to, among other things, adopt a policy of universal DAA treatment of HCV. *Id.* at *20. The *Hoffer* court was motivated in large part by the FDC's "long and sordid history of neglecting HCV-infected inmates" and "continued opposition to the relief granted" in its order. *Id.* at *8. FDC's meager efforts to provide medical care for HCV-infected inmates, which are further detailed in the court's preliminary injunction order, *see Hoffer v. Jones*, 290 F.Supp.3d 1292, 1297-98 (N.D. Fla. Nov. 17, 2017), stand in stark contrast to Defendants' extensive efforts to ensure proper medical care for HCV-infected inmates in Tennessee.[7] More importantly, however, the defendants in *Hoffer* did not provide "*any* medical reason" for their decision not to provide universal DAA treatment. *Hoffer*, 2019 WL 1747074, at *9.

[6] Conversely, a federal court that did consider such evidence was not persuaded, at the preliminary injunction stage, that universal DAA treatment is medically necessary. Buffkin v. Hooks, No. 1:18-cv-502, 2019 WL 1282785, at *10 (M.D. N.C. Mar. 20, 2019).

[7] At the time of its preliminary injunction hearing, with a total prison population of 98,000 and an estimated HCV-infected population of 20,000, FDC had provided DAA treatment to 13 inmates and had not submitted any requests additional funding for the purchase of DAAs. *Hoffer*, 290 F.Supp.3d at 1294, 1298. By contrast, with a total prison population of 21,000 and a known HCV-infected inmate population of 4,740, TDOC has provided DAA treatment to more than 400 inmates and has secured more than $30 million in additional funding for the purchase of DAAs.

Similarly, in *Stafford v. Carter*, No. 1:17-cv-289, 2018 WL 4361639 (S.D. Ind. Sept. 13, 2018), the district court excluded *all* of the defendants' expert witnesses. Id. at **4-6. In the absence of any evidence to the contrary, the *Stafford* court found that the AASLD Guidance represents a nationally accepted standard of care for HCV treatment and that the defendants' failure to provide universal DAA treatment in accordance with that standard constituted deliberate indifference. *Id.* at *20.

Defendants here present verifying medical evidence to show that universal DAA is not medically necessary. Specifically, Drs. Koretz, Gerrity, and Williams state that providing DAA treatment to individuals with fibrosis scores of F0 to F2 is not medically necessary and, given the uncertain long-term effects of DAAs, unadvisable. In light of that evidence, the Court should not be persuaded by the decisions of these other courts.

CONCLUSION

Plaintiffs cannot present evidence to satisfy either the objective or subjective components of their Eighth Amendment claim. HCV is a slow progressing disease that generally takes decades to progress before impairing liver function. Most HCV-infected patients will never progress to cirrhosis. DAAs, while a prudent treatment option for patients in later stages of fibrosis (F3 and F4), are not medically necessary for all patients in earlier stages (F0 to F2). The long-term effects and effectiveness of DAA treatment are unknown, and active monitoring of fibrosis progression constitutes adequate care in those patients. While Defendants acknowledge that HCV is a serious medical condition that requires some medical attention, Plaintiffs cannot show that the care they receive under TDOC's current policies is inadequate or causes serious medical harm. Moreover, because the efficacy of DAA treatment in earlier stages of fibrosis (F0 to F2) is the subject of robust and substantial good faith disagreement between respected members of the medical expert

community, Plaintiffs cannot show that Defendants acted with a subjectively culpable state of mind in implementing those policies. For those reasons, Plaintiffs' Eighth Amendment claim must fail, and this suit must be dismissed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of July 2019, a copy of the foregoing document was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the electronic filing system. Service has thus been made upon Plaintiffs' counsel of record:

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